

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

MAR 2 0 2009

Richard S. Barth, Esq. Frishauf, Holtz, Goodman & Chick, P.C. 220 Fifth Avenue, 16th Fl. New York, NY 10001-7708

In Re: Patent Term Extension Application for U.S. Patent No. 5,795,911

Dear Mr. Barth:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,795,911 for a period of 1,300 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at raul.tamayo@uspto.gov.

Mary C. Till Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

cc: Office of Regulatory Policy

Food and Drug Administration

10903 New Hampshire Ave., Bldg. 51, Rm. 6222

Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: VEREGEN® (sinecatechins)

Docket No.: FDA-2007-E-0460

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO.

5,795,911

(45) ISSUED

: August 18, 1998

(75) INVENTOR

Shu Jun Cheng et al.

(73) PATENT OWNER

Mitsui Norin Co., Ltd. & Cancer Institute

(Hospital), Chinese Academy of Medical Sciences

(95) PRODUCT

VEREGEN® (sinecatechins)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,795,911 based upon the regulatory review of the product VEREGEN® (sinecatechins) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,300 days

from April 10, 2017, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 18th day of March 2009.

JOHN J. DOLL

Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office